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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/757,345 | 01/14/2004 | Sudhir Agrawal | HYB-018US1 | 3490 |

7590 10/03/2007

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|---|---|
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| ART UNIT | PAPER NUMBER |
| 1633 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 10/03/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/757,345 | AGRAWAL ET AL. | |
| | Examiner | Art Unit | |
| | Kevin K. Hill, Ph.D. | 1633 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-26 and 28-146* is/are pending in the application.

4a) Of the above claim(s) *2-26,28-30 and 32-146* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## *Detailed Action*

Applicant has elected the invention of Group I, drawn to an immunomer compound comprising at least two oligonucleotides linked together, wherein Applicant has elected the oligonucleotide linkage species to be "iv", a sugar to a non-nucleotide linker and the "G" moiety species to be "2'-deoxy-7-deazaguanosine". However, upon further consideration, the Examiner has withdrawn the "G" species election requirement.

Election of Applicant's invention(s) was made without traverse.

## *Amendments*

Applicant's response and amendments, filed July 11, 2007, to the prior Office Action is acknowledged. Applicant has cancelled Claim 27, withdrawn Claims 2-26, 28-30 and 32-146, and amended Claims 1 and 31.

Claims 2-26, 28-30 and 32-146 are pending but withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim.

Claims 1 and 31 are under consideration.

## *Priority*

Applicant's claim for the benefit of a prior-filed parent provisional application 60/440,587 filed on January 16, 2003 under 35 U.S.C. 119(e) is acknowledged. Accordingly, the effective priority date of the instant application is granted as January 16, 2003.

### *Response to Amendment*

Applicant's remarks regarding benefit of 60/440,587, as indicated in the Application Data Sheet filed January 14, 2004, is acknowledged.

## *Specification*

### *Sequence compliance*

37 CFR 1.821(d) states: "[w]here the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description of claims, even if the sequence is also embedded in the text or the description or claims of the patent application.

1. **This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2).** However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because sequences are set forth in the specification that lack sequence identifiers.

Figures 2, 7-12, 15-17, 19-20, 23 and 25-30 identify "immunomers" or "oligonucleotides", but do not identify the immunomer or oligonucleotide by their corresponding SEQ ID NO.

Sequences must be assigned a SEQ ID NO. Sequences must be provided in computer readable format (CRF) and on paper. Further, a statement indicating the two formats are the same must also be provided.

**It is often convenient to identify sequences in figures by amending the Brief Description of the Drawings section (see MPEP 244.02).** If the sequences are already present in the sequence listing, it would be remedial to amend the Brief Description of the Drawings or specification to include the appropriate sequence identifiers. Applicants are required to comply with all of the requirements of 37 CFR 1.821 - 1.825. Any response to this office action that fails to meet all of these requirements will be considered non-responsive.

The Examiner notes that in the reply filed July 11, 2007, Table 16 remains unamended, and therefore retains the defective SEQ ID NO identification of the tabulated oligonucleotides discussed in the prior Office Action.

The nature of the noncompliance with the requirements of 37 C.F.R. 1.821 through 1.825 did not preclude the examination of the application on the merits, the results of which are communicated below.

***Response to Amendment***

The Examiner has considered those references in the Information Disclosure Statements filed March 11, 2004 and July 2, 2005, as indicated on PTOL-326 mailed February 7, 2007. To

the effect that the references in the specification are provided in the IDS, said references have been considered.

## *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. **Claims 1 and 31 are rejected under 35 U.S.C. 103(a)** as being unpatentable over Kandimalla et al (Bioorganic & Medicinal Chem. 9:807-813, 2001; *of record in IDS), Cook et al (U.S. 2003/0004325 A1), Rappaport (U.S. 5,126,439), Simmonds et al (WO 99/06422, U.S. equivalent 6,444,682), Yu et al (Bioorganic & Medicinal Chem. Letters 10:2585-2588, 2000; *of record in IDS), Teng et al (U.S. 5,677,437), and Cook et al (U.S. 6,232,463 B1). This is a new rejection.

The claims are drawn to an immunomer compound comprising at least two oligonucleotides linked at their sugars to a non-nucleotidic linker, wherein at least one of the oligonucleotides is an oligonucleotide having an accessible 5' end and comprising an

immunostimulatory dinucleotide having the structure RpG, wherein the "R" moiety has the structure of pyrrolopyrimidine-C and the "G" moiety is guanosine, 2'-deoxyguanosine, 2'-deoxy-7-deazaguanosine", 2'-deoxy-6-thioguanosine, arabinoguanosine, 2'-deoxy-2' substituted-arabinoguanosine, 2'O-substituted-arabinoguanosine, or other non-natural purine.

Kandimalla et al teach the synthesis of phosphorothioate CpG immunostimulatory oligonucleotides comprising variations of the CpG motif, YpG and CpR, respectively, in which the "Y" moiety represents a monocyclic or bicyclic cytosine analog (pg 808, Figures 1 and 2) and the "R" moiety represents a bicyclic guanine analog, including 2' deoxyguanosine, 2'-deoxy-7-deazaguanosine, and other non-natural purine nucleosides (pg 809, Figure 3).

Kandimalla et al do not teach the "G" moiety to be replaced with arabinoguanosine, 2'-deoxy-2'-substituted-arabinoguanosine, 2'-O-substituted-arabinoguanosine. However, at the time of the invention, Cook et al (2003) disclosed sugar-modified oligonucleotides in which one or more nucleosides may be replaced with 2'-deoxy-2'-substitutions, wherein the sugar may be an arabino sugar (pg 2, [0021-0023]; pg 6, [0074]).

Neither Kandimalla et al nor Cook et al (2003) teach the "G" moiety to be replaced with 2'-deoxy-6-thioguanosine; however, at the time of the invention, Rappaport disclosed that 6-thio-guanine is an appropriate substitution for guanine in oligonucleotides (col. 2, lines 22-35).

Neither Kandimalla et al, Cook et al (2003), or Rappaport et al teach the replacement of cytosine with pyrrolopyrimidine-C that possesses the "R" structure shown in Figure 24. However, at the time of the invention, Simmonds et al disclosed novel nucleoside analogs or base analogs having the structure illustrated in Figure 24 of the instant specification (Abstract, pgs 1-2), wherein such novel base analogs may be incorporated into nucleic acids and oligonucleotides (pg 1, lines 5-7; pg 6, lines 1-2).

Neither Kandimalla et al, Cook et al (2003), Rappaport et al nor Simmonds et al teach the phosphorothioate CpG immunostimulatory oligonucleotides to be linked at their 3' ends. However, at the time of the invention, Yu et al taught the synthesis of immunostimulatory compounds comprising at least two CpG containing oligonucleotides linked at their 3' ends via an internucleoside linkage comprising functionalized sugars wherein at least one of the CpG oligonucleotides has an accessible 5' end (pg 2586, Figure 1 and Table 1).

Neither Kandimalla et al, Cook et al (2003), Rappaport et al, Simmonds et al nor Yu et al teach CpG immunostimulatory oligonucleotides to be linked via a functionalized sugar to a non-nucleotidic linker (as defined in the specification, pg 29, lines 6-16). However, at the time of the invention, Teng et al disclosed means of joining two nucleotides by a functionalized sugar linked to a non-nucleotidic linker (col. 4, lines 7-67).

Neither Kandimalla et al, Cook et al (2003), Rappaport et al, Simmonds et al, Yu et al nor Teng et al teach CpG immunostimulatory oligonucleotides to be linked via a functionalized nucleobase. However, at the time of the invention, Cook et al (2001) disclosed that oligonucleotides may comprise functionalized nucleobases so as to provide at least one site of covalent bonding between the oligonucleotide and the target sequence (col. 5, lines 15-32; col. 10, lines 7-41 and 56-59; col. 11, lines 1-37), wherein the heterocyclic base analogs are adapted for placement of a pendant group, such as a crosslinking moiety.

All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination(s) would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute a guanine base for another guanine analog because the practice of substituting guanine for the claimed guanine analogs were known in the art. Absent evidence to the contrary, nothing non-obvious is seen with replacing a guanine base with a non-natural purine having a structure substantially similar to guanine as claimed because the simple substitution of one guanine analog for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

It also would have been obvious to substitute a cytosine base with a pyrrolopyrimidine-C nucleoside analog having the structure shown in Figure 24 because the art has long-recognized that the replacement of cytosine with pyrrolopyrimidine-C does not substantially affect the functioning of the nucleotide in any substantial manner. Thus, replacement of cytosine with pyrrolopyrimidine-C is not believed to substantially alter the structure, e.g., secondary, tertiary or other structure, of any nucleic acid strand which substitutes one or more cytosines with one or

more pyrrolopyrimidine-C molecules. Such properties provide for the ability to use pyrrolopyrimidine-C in place of cytosine in many applications, such as in nucleic acid strands, primers, probes, hybridization assays, investigation of nucleic acid-nucleic acid interaction, investigation of nucleic acid-protein interactions, investigation of nucleoside-protein interactions, for therapeutic uses, and the like. The simple substitution of a cytosine for a cytosine analog would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

It also would have been obvious to join two oligonucleotides comprising "RpG" immunostimulatory motifs substantially as claimed with a reasonable chance of success because Yu et al successfully demonstrated the ability to join two oligonucleotides at their 3' ends. An artisan would have been motivated to join two oligonucleotides at their 3' ends because Yu et al taught that immunostimulatory oligonucleotides linked at their 3' end and possessing at least one accessible 5' end had greater immunostimulatory effect and potentially longer half-lives than individual (non-linked) oligonucleotides or those oligonucleotides linked in combinations other than 3' to 3' (e.g. pg 2587, Figure 2; pg 2588, col. 2, ¶1).

It also would have been obvious to one of ordinary skill in the art to join two oligonucleotides by linking their 3' ends, using an internucleoside linkage, a functionalized nucleobase or a sugar to a non-nucleotidic linker because methods of joining, bonding, attaching or crosslinking nucleic acids were known in the art. The simple substitution of one known linkage means for another known linkage means would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Thus, the invention as a whole is *prima facie* obvious.

## ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

*Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. **The prior rejection of Claims 1 and31 on the ground of nonstatutory obviousness-type double patenting** over Claims 1-2 of copending Application No. 10/279,684 **is withdrawn** in light of the cancellation of claims 1-36 in the copending application (papers filed May 9, 2007).

4. **Claims 1 and 31 are newly provisionally rejected** on the ground of nonstatutory obviousness-type double patenting over Claims 37, 39, 40 and 52-59 of copending Application No. 10/279,684.

**Note:** A Notice of Allowance of Claims 37, 39, 40 and 42-60 of 10/279,684 was mailed August 6, 2007.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim immunomers having at least two oligonucleotides linked together by a non-nucleotidic linker, wherein the internucleoside linkage is a phosphorothioate, wherein at least one of the oligonucleotides is an oligonucleotide having an accessible 5' end and comprising an immunostimulatory dinucleotide having the structure RpG, wherein the "R" a non-natural pyrimidine nucleoside and wherein the "G" moiety is guanosine, 2'-deoxyguanosine, 2'-deoxy-7-deazaguanosine", 2'-deoxy-6-thioguanosine, arabinoguanosine, 2'-deoxy-2' substituted-arabinoguanosine, 2'O-substituted-arabinoguanosine, or other non-natural purine. Because the instant claim uses the generic term "internucleoside linkage", the Examiner has looked to the specification for a definition to better understand the invention, wherein a genus of internucleotide linkages are disclosed (pg 7, lines 5-8) substantially as claimed in the co-pending

application, and wherein the immunomer may be conjugated to an antigen (pg 7, lines 16-20). Thus, the composition(s) of the instant claim(s) is reasonably embraced by the copending application.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

5. **Claim 1 stands provisionally rejected** on the ground of nonstatutory obviousness-type double patenting over Claim 1 of copending Application No. 10/361,111.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim immunomers having at least two oligonucleotides linked together by a non-nucleotidic linker, wherein the internucleoside linkage is modified, wherein at least one of the oligonucleotides is an oligonucleotide having an accessible 5' end and comprising an immunostimulatory dinucleotide having the structure of a non-natural pyrimidine nucleoside and a non-natural purine nucleoside. Thus, the composition(s) of the instant claim(s) is reasonably embraced by the copending application.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

6. **Claims 1 and 31 are provisionally rejected** on the ground of nonstatutory obviousness-type double patenting over Claim 12 of copending Application No. 10/694,383. This is a new rejection.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim immunostimulatory oligonucleotide compositions comprising an immunostimulatory dinucleotide having the structure of a non-natural pyrimidine nucleoside and a non-natural purine nucleoside.

The claims are drawn to an immunostimulatory oligonucleotide compound comprising a "YpZ" motif, wherein the "Y" moiety is a non-natural pyrimidine and the "Z" moiety is guanosine, 2'-deoxy-guanosine or a non-natural purine nucleoside. Because the claim uses the generic term "compound", the Examiner has looked to the specification for a description of the invention, wherein the specification discloses that the immunostimulatory oligonucleotides may be joined by 3' to 3' linkages (pg 10, line 23-pg 12, line 9). Thus, instantly claimed immunomer composition(s) are reasonably embraced by immunostimulatory oligonucleotide(s) of the copending application.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

7. **Claims 1 and 31 are provisionally rejected** on the ground of nonstatutory obviousness-type double patenting over Claims 20-21 of copending Application No. 10/694,586. This is a new rejection.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim immunostimulatory oligonucleotide compositions comprising an immunostimulatory dinucleotide having the structure of a non-natural pyrimidine nucleoside and a non-natural purine nucleoside.

The claims are drawn to an immunostimulatory oligonucleotide compound comprising a "CpG" motif, wherein the "C" moiety is a non-natural pyrimidine and the "G" moiety is a natural or non-natural pyrimidine nucleoside. Because the claim uses the generic term "compound", the Examiner has looked to the specification for a description of the invention, wherein the specification discloses that the immunostimulatory oligonucleotides may be joined by 3' to 3' linkages (pg 5, lines 18-20). Thus, instantly claimed immunomer composition(s) are reasonably embraced by immunostimulatory oligonucleotide(s) of the copending application.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

8. **Claims 1 and 31 are provisionally rejected** on the ground of nonstatutory obviousness-type double patenting over Claim 18 of copending Application No. 10/865,245. This is a new rejection.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim immunostimulatory oligonucleotide compositions comprising an immunostimulatory dinucleotide having the structure of a non-natural pyrimidine nucleoside and a non-natural purine nucleoside.

The claims are drawn to an immunostimulatory oligonucleotide compound comprising a "CpG" motif, wherein the "C" moiety is a non-natural pyrimidine and the "G" moiety is a natural or non-natural pyrimidine nucleoside, wherein the immunostimulatory oligonucleotides

may be joined by 3' to 3' linkages. Thus, instantly claimed immunomer composition(s) are reasonably embraced by immunostimulatory oligonucleotide(s) of the copending application.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

9. **Claims 1 and 31 are provisionally rejected** on the ground of nonstatutory obviousness-type double patenting over Claims 1-5, 16, 21-23 of copending Application No. 10/925,873. This is a new rejection.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim immunostimulatory oligonucleotide compositions comprising an immunostimulatory dinucleotide having the structure of a non-natural pyrimidine nucleoside and a non-natural purine nucleoside.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim immunomers having at least two oligonucleotides linked together by a non-nucleotidic linker, wherein the internucleoside linkage is a phosphorothioate, wherein at least one of the oligonucleotides is an oligonucleotide having an accessible 5' end and comprising an immunostimulatory dinucleotide having the structure C*pG*, wherein the "C*" a non-natural pyrimidine nucleoside and wherein the "G*" moiety is guanosine, 2'-deoxyguanosine, 2'-deoxy-7-deazaguanosine", 2'-deoxy-6-thioguanosine, arabinoguanosine, 2'-deoxy-2' substituted-arabinoguanosine, 2'O-substituted-arabinoguanosine, or other non-natural purine. Because the instant claim uses the generic term "internucleoside linkage", the Examiner has looked to the specification for a definition to better understand the invention, wherein a genus of internucleotide linkages are disclosed (pg 7, lines 5-8) substantially as claimed in the co-pending application, and wherein the immunomer may be conjugated to an antigen (pg 7, lines 16-20). Thus, the composition(s) of the instant claim(s) is reasonably embraced by the copending application.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

10. **The prior rejection of Claims 1 and 31 on the ground of nonstatutory obviousness-type double patenting** over Claims 1, 11 and 16 of copending Application No. 11/153,054 **is withdrawn** in light of the amendments to the claims in the copending application (papers filed May 30, 2007).

11. **Claims 1 and 31 are newly provisionally rejected** on the ground of nonstatutory obviousness-type double patenting over Claims 11-13 and 16 of copending Application No. 11/153,054.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim immunostimulatory oligonucleotide compositions comprising an immunostimulatory dinucleotide having the structure of a non-natural pyrimidine nucleoside and a non-natural purine nucleoside.

Because the claims of copending Application No. 11/153,054 recite generically "CpG, C*pG, C*pG* and CpG*", the Examiner has looked to the specification for definitions of the "C" and "G" moieties so as to better understand the invention. The specification discloses that C* is... 1-(2'-deoxy-β-D-ribofuranosyl)-2-oxo-7-deaza-8-methyl-purine, and that G* is... 2'-deoxy-7-deazaguanosine (pg 1, [0010]), wherein the non-nucleotidic linker may be a 3'-3' linkage (pg 3, [0032]). Thus, instantly claimed immunomer composition(s) anticipate immunostimulatory oligonucleotide(s) of the copending application.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

12. **Claims 1 and 31 stand provisionally rejected** on the ground of nonstatutory obviousness-type double patenting over Claims 1 and 4 of copending Application No. 11/174,002.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim immunostimulatory oligonucleotide compositions comprising an immunostimulatory dinucleotide having the structure of a non-natural pyrimidine nucleoside and a natural or non-natural purine nucleoside.

Thus, instantly claimed immunomer composition(s) anticipate immunostimulatory oligonucleotide(s) of the copending application.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

***Response to Amendment***

Applicants request that the Examiner withdraw the rejection and allow the application to issue as a patent (See MPEP §804(I)(B)). Applicants will then consider filing a Terminal Disclaimer or take any other action deemed necessary in the later filed copending applications.

The provisional nonstatutory obviousness-type double patenting rejections will be maintained until all claims have been deemed otherwise in condition for allowance or allowable.

## *Conclusion*

13. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AKA
Pyrrolo-dC

Q. JANICE LI, M.D.
PRIMARY EXAMINER